Rational Pharmaceutical Management Plus
Pre-assessment Visit to Fujian Province, China: Trip Report
November- December 2004

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Abstract

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Key Words

Tuberculosis, TB, drug management, China, pre-assessment

Contents

Acronyms

CDC	Chinese Center for Disease Control and Prevention
DMTB	Drug Management for Tuberculosis
DAS	Drug Availability Study
DUS	Drug Use Study
FDC	Fixed Dose Combination Drugs
FLO	Foreign Loan Office
GMP	Good Manufacturing Practices
MSH	Management Sciences for Health
MOH	Ministry of Health
NCTB	National Center for Tuberculosis Control and Treatment
RPM Plus	Rational Pharmaceutical Management Plus [Program]
STG	Standard Treatment Guidelines
SDA	State Drug Authority
TB	Tuberculosis
USAID	US Agency for International Development
VHW	Village Health Worker
WB	World Bank
WHO	World Health Organization

Background

China is one of the countries having a high incidence of TB, estimated around 107 per 100,000 of the population. It ranks second globally in terms of the estimated number of TB cases. It appears that the incidence and case detection rate of TB patients is rising in China. Hence, there is a growing need for utilizing efficient management systems for supplying TB drugs to TB patients throughout China.

Due to these conditions, the National Center for Tuberculosis (NCTB) / Chinese Center for Disease Control and Prevention (CDC) has shown interest in strengthening the national TB drug management program. It appears that a formal assessment of the TB drug management program has not been undertaken so far in any part of China. Hence, this pre-assessment visit was arranged by World Health Organization in China (WHO) and CDC with a view to undertaking an assessment of the TB drug management system very shortly with technical assistance from MSH.

This trip to China was undertaken under the Rational Pharmaceutical Management Plus Program (RPM Plus), of Management Sciences for Health (MSH) in November 2004. Discussions began in mid-2004 on the potential involvement of RPM Plus in providing technical assistance to strengthen pharmaceutical management of tuberculosis (TB) in China. Prior to undertaking this initial visit, RPM Plus reviewed existing information on TB drug management in China, and developed a summary, entitled, "TB Pharmaceutical Management Situation in China." In consultation with USAID/Washington USAID/RMD/A in Bangkok, and WHO/China, RPM Plus developed a scope of work for an initial visit to Beijing and a selected province. This trip report describes nature of work undertaken in China from November 29 to December 3, 2004. A detailed description of work completed is included in the section, titled "Activities."

Purpose of Trip

The purposes of this visit included the following: participate in a field visit to Fujian Province to learn about TB drug management at national, provincial, county, and other levels; meet with representatives of the US Embassy, WHO/China, CDC/China, and other organizations to brief them on the proposed RPM Plus approach to assessing TB drug management practices; discuss their perceptions of TB drug management issues and impressions from the field visit; and to plan next steps for conducting the TB drug management assessment using the tool "Drug Management for Tuberculosis" (DMTB) developed by MSH for assessing performance of Tuberculosis (TB) drug management program in some selected province(s) of China.

Scope of Work

The scope of work for Vimal Dias for this visit:

- Provide a briefing/debriefing to health officers of the US Embassy in Beijing or in Bangkok, as requested
- Meet with representatives of WHO/China, CDC/China, and the National TB program manager to discuss their concerns about pharmaceutical supply management for TB
- Participate in a field visit to Fujian Province to learn about drug management systems at provincial, county, and local levels and to identify potential sources of data for an assessment
- Obtain copies of existing documentation regarding drug management aspects of the National TB Program, including studies, reports, and evaluations
- Identify potential partners/ subcontractors that may be engaged in the process

Activities

Following key activities as outlined in the scope of work were accomplished during the visit. A substantial part of the time was involved in undertaking a field trip to Fujian Province for observing the operation of the TB drug management system at provincial, prefecture and county levels. This visit provided a good overview of the current operation of the TB drug management system. However, it is important to mention that observations made during the field visit and described in this report may not be representative of practices employed in other parts of China. Further, much time was spent with staff attached to CDC, MOH and WHO in introducing the tool "Drug Management for Tuberculosis" (DMTB), which would be employed for undertaking the assessment.

Discussions were also held with WHO and CDC staff in making plans for undertaking a package of activities for strengthening TB drug management. See the section, Next Steps, below for details.

Nature of DMTB Assessment

Procuring TB drugs for a country of the size of China with a high burden of TB requires a great deal of financial resources. Further, the cost of maintaining a pharmaceutical logistics system to distribute and hold stocks of TB drugs at nearly 3,000 TB dispensaries throughout China is also very significant. In addition to any financial benefits to be derived through effective drug management, it is also important to ensure that there is an uninterrupted supply of good quality TB drugs to county level for TB patients to receive proper treatment, based on CDC/WHO standard treatment guidelines.

Before making any attempt to identify any weak spots of the TB pharmaceutical management system, it would be important to undertake a proper assessment of the TB drug management program covering the four key functions of the drug management cycle, namely; selection, procurement, distribution and use of TB drugs. It is proposed that "Drug Management for Tuberculosis" (DMTB), a tool developed by MSH for assessing TB drug management programs be employed for this purpose. MSH has successfully employed DMTB in assessing TB drug management programs in several countries.

DMTB uses an indicator based approach assessing drug management programs. It uses a set of indicators for describing a particular situation regarding the "Availability of TB Drugs", referred to as the "Drug Availability Study" (DAS). Another set of indicators are used for describing drug use practices under another study referred to as the "Drug Use Study" (DUS).

China is a very large country and, hence, it would not be at all practical to use DMTB in all 31 provinces of China. Therefore, the DMTB tool is expected to be used in two provinces on a sample basis for assessing the performance of the drug management program. Information and measurement taken in relation to operations of the drug management program would be taken at central, provincial, prefecture and county levels, based on a suitable sampling plan to be developed.

Based on the information collected during the DMTB assessment and values generated for various study indicators, it would be possible to identify certain weak spots of the TB drug management programs in surveyed provinces. Accordingly, a set of specific interventions would be developed to address these drug management problems. An action plan for developing new systems and procedures to overcome current problems facing the program has been developed in terms of a 5 phase package of activities (Next Steps).

TB Drug Procurement

Basic information relating to the procurement of TB drugs by the Foreign Loan Office (FLO) of the MOH and NCTB / CDC was gathered. These 2 organizations are responsible for procuring all TB drugs entering the public sector drug supply system using funds provided by the Chinese Government and other donors such as the World Bank (WB) and JICA.

There are many Procurement Agents and Funding Sources for supplying TB drugs to the public sector in China. However, the implementing agency for managing and supplying TB drugs is the CDC. The following table provides a summary of these procurement activities.

Procurement Agent	**Funding Source**	**Procurement Method**	**Number of Provinces serviced**	**Suppliers**	**Lead Time in Days ***	**Procurement Value / % in FY -2003**
Foreign Loan Office Beijing	50% by World Bank & balance by Government	ICB	4	Local (4-5)	90	USD 300,000 (7%)
CDC Beijing	Government	ICB	15 in all. (50% for 8 provinces)			25 Million Yuan (47%) USD 3 Million
CDC Beijing	Global Fund	ICB	1			2%
JICA	Japanese Government	ICB	12	Local		44%

* After award of tender.

Since 2004, TB drug products are expected to be procured from local drug manufacturers who have been issued with Good Manufacturing Practices (GMP) certificates by the State Drug Administration (SDA). It appears that a very few (about 2 manufacturers) are producing the entire TB drugs needs of China, which also happen to be a very substantial part of the global TB drugs needs. However, time did not permit a meeting with SDA to obtain details regarding the GMP certification process and also the status regarding the manufacture of Fixed Dose Combination (FDC) drugs in China.

Interviews held with Procurement Staff also indicated that all batches of TB drugs are tested by Provincial Labs and these are re-checked by the Laboratory at national level on a sample basis. It was not possible to get details of tests carried out. However, it appears that tests for Bioavailability / Bioequivalence are not undertaken for TB drugs.

Persons responsible for drug management at central, provincial, prefecture levels and at TB Dispensaries didn't report any significant problems relating to quality of TB drugs during the field visit made to Fujian province.

Appendix No. 1 provides information on TB drug prices and quantities procured by the FLO and CDC, using World Bank and JICA funds in 2004. The prices indicated are for blister packs for daily intake of HRZE, HR, HRE. All prices include transport charges up to the level of all 31 provincial TB drug warehouses. It is seen that WB prices are significantly higher when compared to CDC prices for JICA supported drugs. This could mainly be on account of the fact that quantities procured by WB funds is significantly smaller.

No attempt was made to compare CDC and WB drug prices with those appearing in MSH "International Drug Price Indicator Guide", as these prices are for a set of drugs found in a particular blister pack and not for individual drugs within blister packs.

However, the following analysis has been provided in respect of Strepotomycin and Water for injection, as these are procured as individual products.

Product Name	**Int. Indicator Median Price 2003 USD ***	**CDC / JICA Price in USD**	**CDC / JICA Price as a % of Int. Indicator Price**	**WB / FLO Price in USD**	**WB / FLO Price as a % of Int. Indicator Price**
Streptomycin Inj. 1 G Powder	0.1325	0.03743	28.24%	0.05917	44.65%
Water for Injection 5 cc.	0.0341	0.0169	49.56%	NP	

** Exchange rate used: 1 USD = 8.28 Yuan*
International Indicator Prices have been adjusted upwards by a factor of 25% to reflect; ocean freight, insurance and inland transportation costs up to the level of all provincial drug stores.

NP = Not procured by WB/FLO

The above analysis shows that FLO and CDC prices compare very favorably with median international indicator drug prices. This is especially so in the case of CDC/JICA products.

Observations from the Field Visit to Fujian Province

Introduction

Following are some key observations made during the field trip to Fujian Province on 11.30.04, relating to important features of the TB drug management system. During the visit, organizations listed below were visited for conducting interviews and gathering information related to the management of the TB program and drugs.

- Provincial TB Office in Fuzhou city
- Fujian Province TB Drug Store
- Fuzhou Prefecture TB Office in Fuzhou city
- Fuzhou Prefecture TB Drug Store
- Yan Ping TB Dispensary in Fujian Province

The team visiting Fujian Province consisted of the following.

- Dr. Lai Yuji, NCTB / CDC, Beijing
- Dr. Wang Lin, NCTB / CDC, Beijing
- Dr. Lin Yan, WHO Beijing
- Vim Dias, Management Sciences for Health, (MSH), USA

Distribution from Central Level

There is no Central TB Drug Store in Beijing at central level. Suppliers who are awarded procurement contracts supply TB drugs directly to the 31 Provincial TB Drug Stores. A stock of 25% of the annual drug order is retained as a buffer stock by the supplier to meet emergency needs.

Appendix No. 2 provides a flow diagram of the TB Drug Supply System, showing location of storages at different levels of the system such as at; provincial, prefecture and county, frequency of delivery between levels and nature of inventory control systems employed for the drug supply system operating in Fujian province. However, features of systems employed in other provinces / prefectures may be some what different.

Storekeeping Practices

<u>Provincial TB Drug Store at Fujian Province</u>

This is a small store measuring about 7 square meters. Stocks of TB drugs held here mainly to serve as a buffer, as most stocks are released to Prefecture Drug Stores when ever fresh drug stocks are received from a supplier. Fujian Province receives drugs procured by the FLO once a year and balance 50% of drugs procured by CDC twice a year.

Stocks were well maintained on wooden racks and stock cards were employed for recording receipts, issues and balances. Separate stock records were maintained for recording inventory

transactions relating to Government funded and World Bank Funded drugs. Storekeepers were complaining that this procedure leads to additional work owing to duplication of record keeping activities.

According to the staff employed at this store, none of the TB drug products have ever been written off during years 2003 and 2004 on account of expiry. Further, there have not been any stock outs with respect to any of the 6 TB drug products during 2003 and 2004. However, time did not permit a thorough examination of records to substantiate such claims.

TB Drug Store at Fuzhou Prefecture

This is a relatively large store measuring about 30 square meters with adequate space for receiving and storage of drugs. Levels of TB drugs held here were relatively higher compared to provincial level. Stocks were well maintained and held separately for Government and World Bank funded stocks on wooden racks. Stock cards backed up by computer spread sheets were employed for recording receipts, issues and balances. Separate stock records were maintained for recording inventory transactions relating to Government and World Bank Funded drugs. Staff here too was complaining about the duplication of record keeping.

According to the staff employed at this store, no TB drugs have been written off during years 2003 and 2004 on account of expiry. Further, there have not been any stock outs of TB drugs during years 2003 and 2004. However, time did not permit a thorough examination of records to substantiate such claims.

TB Dispensary Store at Yan Ping

There is a pharmacy dispensing TB drugs to patients and a small store for stocking TB drugs to meet up to around 3 - 4 months of drug needs. Stocks were well maintained on wooden racks and cupboards. Stock record cards were employed for recording receipts, issues and balances. Separate stock records were maintained for recording inventory transactions relating to Government and World Bank funded drugs.

According to the Dispensary staff, no TB drugs have been written off during years 2003 and 2004 on account of expiry. Further, there have not been any stock outs relating to any of the 6 TB drug products during years 2003 and 2004.

Inventory Control Systems

Between Provincial and Prefecture Levels

There is no formal inventory control system employing any Minimum / Re-order Levels for controlling drug inventories between these 2 levels. A Push System is employed by the Provincial Store for distributing drugs to all prefectures, based on previously determined needs, when ever fresh drug stocks are received at Provincial level. Usually drugs are distributed to prefecture level twice a year.

Between Prefecture and Dispensary Levels

There is no formal inventory control system employing any Minimum / Re-order Levels for controlling drug inventories between these 2 levels. A Push System is employed by the Prefecture Drug Store for distributing drugs to 13 TB Drug Dispensaries in the Prefecture 4 times a year, based on previously determined needs. However, in addition to this supply mechanism, TB dispensaries with high case detection rates are permitted to place additional orders using a Pull System whenever more drugs are needed by them.

The closest Dispensary to the Prefecture Drug Store was located 5 kms away, while the furthest one was located over 100 kms away. A combination of a Delivery and a Collection method was employed for drug distribution.

Quantifying TB Drug Needs

A bottom up approach is employed annually for estimating TB drug needs at Prefecture level. Staff from all TB Dispensaries is involved in this annual exercise. The essential steps involved in this process are as following:

- Review cases detected during the previous planning period by individual TB Dispensaries. In case of facilities with low case detection rates, a new rate is set for the next planning period in line with attainable targets. Information for individual facilities is aggregated to develop Prefecture needs.
- Estimate stock levels of individual TB drug products likely to be in stock at the beginning of the next planning period. This includes stocks held at all TB Dispensaries and at Prefecture level.
- Aggregated prefecture needs are submitted to Provincial level to develop Provincial drug needs.
- Similarly, Provincial needs are aggregated to formulate national needs including provision of buffer stocks.

Drug Use Practices

The Dispensary that was visited during the field visit, or any others do not have a copy of a Standard Treatment Guideline (STG) for treating TB patients. However, the fact that daily intake of TB drugs for different categories of patients are provided in blister packs, has greatly helped in prescribing according to WHO/CDC treatment guidelines.

The dispensary uses the following 6 types of TB drugs and medical supplies for treating following types of patients.

Blister Pack Type/Drug Name	Patient Types
1. HRZE	Intensive phase, new smear (+) cases, smear (+)ve re-treatment cases initial, serious smear (-)ve cases initial phase.
2. HR	Continuous phase, new smear (+) ve cases
3. S	Initial phase of smear (+)ve re-treatment cases
4. HRE	Continuous phase of smear (+)ve re-treatment cases
5.Water for Injection	
6.Disposable Syringe 5 cc.	

Where, H = Isoniazid tablet, R = Rifampicin Capsule, Z = Pyrazinamide tablet and E = Ethambutol Tablet and S = Streptomycin Vial.

A Profile of the TB Program in Fujian Province:

Following is a brief outline of key features of the TB Program in Fujian Province, based on the information gathered and observations made during the one day field visit. Information gathered at; provincial, prefecture and county levels are provided below.

Fujian Province

Population = 34 Million, Estimated number of cases per 100,000 = 138, CDR = 55%

Number of TB Dispensaries in province = 96, Current DOTS coverage 100%.

Fuzhou Prefecture

Population = 5.97, Million, Case Detection Rate (CDR) = 40% and 2004 target is 62%, Cure Rate = 86.10%.

Number of TB Dispensaries in Prefecture = 13.

- Yan Ping TB Dispensary
    - Catchment area served by TB Dispensary is approximately a radius of 70 km.
    - Average number of TB patients treated per day = 15.
    - Staffed by; 2 Doctors, 1 Nurse, 1 trained Lab Technician, 1 Radiologist, 1 Nurse trained as a Pharmacists and a Clerk. Total staff is 7.

- TB patients are treated free of charge except for smear negative cases. Even for this class of patients, very poor patients are provided free treatment provided they are properly certified. Other smear negative patients are charged 80 to 90 Yuan for drugs per month, 1Yuan for sputum test, 20 Yuan a Liver Function Test.

- Dispensary staff is paid 20 Yuan per case when a patient is fully cured as an incentive.

- Patients are provided one month supply of drugs at a time. They are expected to bring back their empty blister packs when returning to the dispensary for re-supplies.

- The TB Dispensary follows a passive approach to case detection.

- The different ways in which the dispensary attracts patients are as follows.

    - About 50-60% of patients are referred by hospitals and Village Health Workers (VHW)s.
    - About 20% of patients visit the dispensary on their own accord.
    - About 20% of patients are referred by their relatives and friends.

- The dispensary provides TB Drug Reports on a monthly basis to Prefecture level indicating current stock levels and usage rates.

- Township/village level doctors are expected to observe and monitor treatment of patients.

An Outline of Key Preparatory Activities for Using DMTB

During the presentation made on the use of DMTB as a tool for assessing performance of the TB drug management program, certain key activities were identified to be undertaken prior to commencement of the assessment in selected provinces. The type of work required for undertaking these activities have been discussed in detail with CDC and WHO staff. These activities would need to be planned and executed properly if good results are to be expected from the assessment.

- Adaptation of MSH survey instruments to the country situation.
- Translation of all survey instruments to Chinese.
- Formulating a list of Tracer TB drugs.
- Selection of the survey team consisting of: Drug Logistics Experts for work at warehouses, Pharmacists/Physicians for Drug Use Surveys at TB Dispensaries and data collectors to work at drug stores, dispensaries and staff for supervision.
- Preparing job descriptions for data collectors and supervisors.
- Training of data collectors and field supervisors.
- Finalization of all survey tools.

- Finalization of the sampling methodology, sample sizes and selection of individual Health facilities / Drug warehouses / patient records, patients for exit poll interviews and simulated purchases from retail shops etc.
- Development of a database for capturing survey information.
- Creation of a time line for undertaking the assessment.
- Development of an operations budget.

A Timeline for the DMTB Assessment

Discussions were held with CDC and WHO staff to develop a possible timeline for undertaking the proposed assessment. However, it was felt that a realistic timeline can not be developed as at present, without making definite decisions regarding some of the basic issues such as the sampling plan and other issues mentioned in section 4 above. A tentative timeline has however been developed and presented in Appendix No.3. This would be modified based on decisions to be taken during the next visit to China, planned in January 2005 under phase 2 of the project.

Collaborators and Partners

The key partners for conducting the proposed assessment are; WHO China and the National Center for Tuberculosis Control and Prevention (NCTB) of the Chinese Center for Disease Control and Prevention (CDC) of the Ministry of Health (MOH). Work on the assessment is expected to commence in January 2005 and would be co-financed by WHO China and the United States Agency for International Development (USAID).

Liu Haitao from the MOH, responsible for TB activities, agreed to using DMTB in 2 selected provinces as per time schedule presented by MSH and WHO. This agreement was reached at a meeting held at the MOH on 12.3.04, based on the presentation made on use of DMTB as a tool for assessing performance of TB drug management programs and how it could be adapted for use in China. Mr. Liu and other members from CDC were also introduced to activities that have been planned after the completion of the DMTB assessment, such plans for strengthening TB drug management systems. The proposed 5 phase plan of action was accepted in principle. See section 4C for details.

Dr. Daniel Chen of WHO participated in all meetings held with CDC and MOH and is in agreement with proposed plans.

Adjustments to Planned Activities

No major adjustments were made to activities planned during this visit.

Lessons Learned

Conclusions and Recommendations

This visit to China was not meant in any way to commence the assessment of the TB drug management system using DMTB, but only to undertake a pre-assessment as preparation for the actual assessment expected to start in January 2005. Two key pieces of work were planned during this visit. The first one was to introduce the use of DMTB as a tool for assessing performance of TB drug management systems to WHO and CDC staff. The other was to undertake a field visit to Fujian province to observe the operation of the TB drug management program. These two objectives were achieved during this visit.

Even though features of the TB management systems used in Fujian province may not be altogether representative of national operations as a whole, the visit to Fujian province proved to be useful in providing an insight to key operating characteristics of the TB drug logistics system. Operating features observed at different levels of the logistics system has been documented in Appendix No.2.

The field visit did not reveal any serious problems relating to TB drug management and use. Losses due to drug expiry or stock outs had also never occurred during years 2003 and 2004 in respect of any TB drug products, as per interviews held with TB staff. However, time did not permit verification of these claims based on stock cards and other records.

There is no TB Drug Management Manual, describing standard operating procedures for functions such as; quantifying drug needs, storekeeping, inventory control, distribution and management information systems. It appears that a draft operations manual is available, needs to be completed. Now that a decision has been made to use DMTB, it would be useful to postpone this activity until such time as new systems and procedures have been developed for TB drug management as suggested in this report.

It is difficult and premature to make any specific diagnosis regarding the performance of the drug supply system without first undertaking a proper assessment using DMTB. However, from initial observations, it appears that the drug management system could profit from use of; inventory control systems linked to recent case detection rates and controlled use of buffer stocks. It also appears that there could be room for strengthening current methods employed for quantifying TB drug needs. This is particularly so as shelf life of TB drugs procured is limited to 2 years.

During this one week visit, several meetings were held with WHO, CDC and MOH staff to discuss many issues relating to use of DMTB and how best to introduce it in selected provinces in China. At the meeting held on 12.3.04, Mr. Liu Haitao of the MOH indicated his willingness to employ DMTB in 2 selected provinces. The selection of individual provinces with relatively weak TB drug management systems would be decided during the next visit to China scheduled for January 2005. Mr. Liu was also agreeable to following the 5 phase package of activities for strengthening TB drug management practices outlined.

It appears that this pre-assessment visit has progressed according to plan, paving the way to commence preparatory work for the introduction of DMTB in January 2005.

Key Points to Remember

It is important to remember that DMTB as a tool would only be capable of highlighting certain weaknesses or problems associated with the TB drug management system through use of indicators developed for drug availability and use. In other words it would not be capable of solving or recommending specific interventions for overcoming any problems / weak spots that may have been identified through DMTB. Development of specific interventions for strengthening TB drug management would undertaken as a separate activity as outlined in the 5 phase package of activities described below. This fact has been clearly explained to and agreed with by CDC Staff during meetings and presentations held in introducing DMTB.

Potential Future Collaboration

The nature of work to be undertaken as part of a package of activities developed for strengthening TB drug management in China is described in the next section. The WHO, CDC and MOH have all expressed their willingness to work with MSH in undertaking this series of activities for improving the management of TB drugs.

Next Steps

Priorities

During and prior to using DMTB tool in selected survey provinces, CDC staff at central, provincial and prefecture levels would need to devote significant amounts of time to certain activities connected with use of DMTB. Hence, it would be important for CDC and WHO staff to take into account this need when developing their work plans over the first quarter of 2005.

Agreements or Understandings with Counterparts

No new agreements or understandings were made in writing or verbally with any counterparts, except a proposal for undertaking a package of activities as described in this section.

Important Upcoming Activities or Benchmarks in Program

It was decided to undertake activities for strengthening TB drug management practices in 5 separate phases. The first phase consists of work connected with the pre-assessment which has been already completed. The nature of important activities planned under other phases of the project is described below.

First Phase

The pre-assessment survey to gather basic information relating to the operation of the TB drug management program and introducing DMTB to major stakeholders has been completed in December 2004.

Second phase

The second phase for planning the survey is scheduled for January 2005. This phase would include the following activities:

- Specific data collection activities appropriate for use at different levels and different sources for collecting data, data collection forms, to be developed and presented to WHO / CDC prior to the next visit to China in January 2005.
- Develop time lines for key activities.
- Discuss proposed approach to data collection, use of appropriate indicators, survey methodology and composition of survey team with key stakeholders.
- Discuss sampling methodology and sampling plan in detail.
- Discuss composition of survey team.
- Finalize features of the DMTB tool to be used in China.

Third phase

Scheduled for February 2005:

- Providing training on the use of DMTB tool.
- Field test the tool in a prefecture close to Beijing.
- Modify DMTB tool based on feedback received from the field test if needed.

Fourth phase

Scheduled for April 2005:

- After data collection, data entry and development of indicators, assist in interpreting indicators.
- Prepare draft list of recommendations outlining specific interventions necessary to strengthen TB drug management systems.
- Discuss proposed interventions with all major stakeholders and select specific interventions which are key to improving performance and also those which are relatively easy to implement.
- Gain acceptance and commitment of CDC and other stakeholders for implementing recommendations agreed upon.

Fifth phase

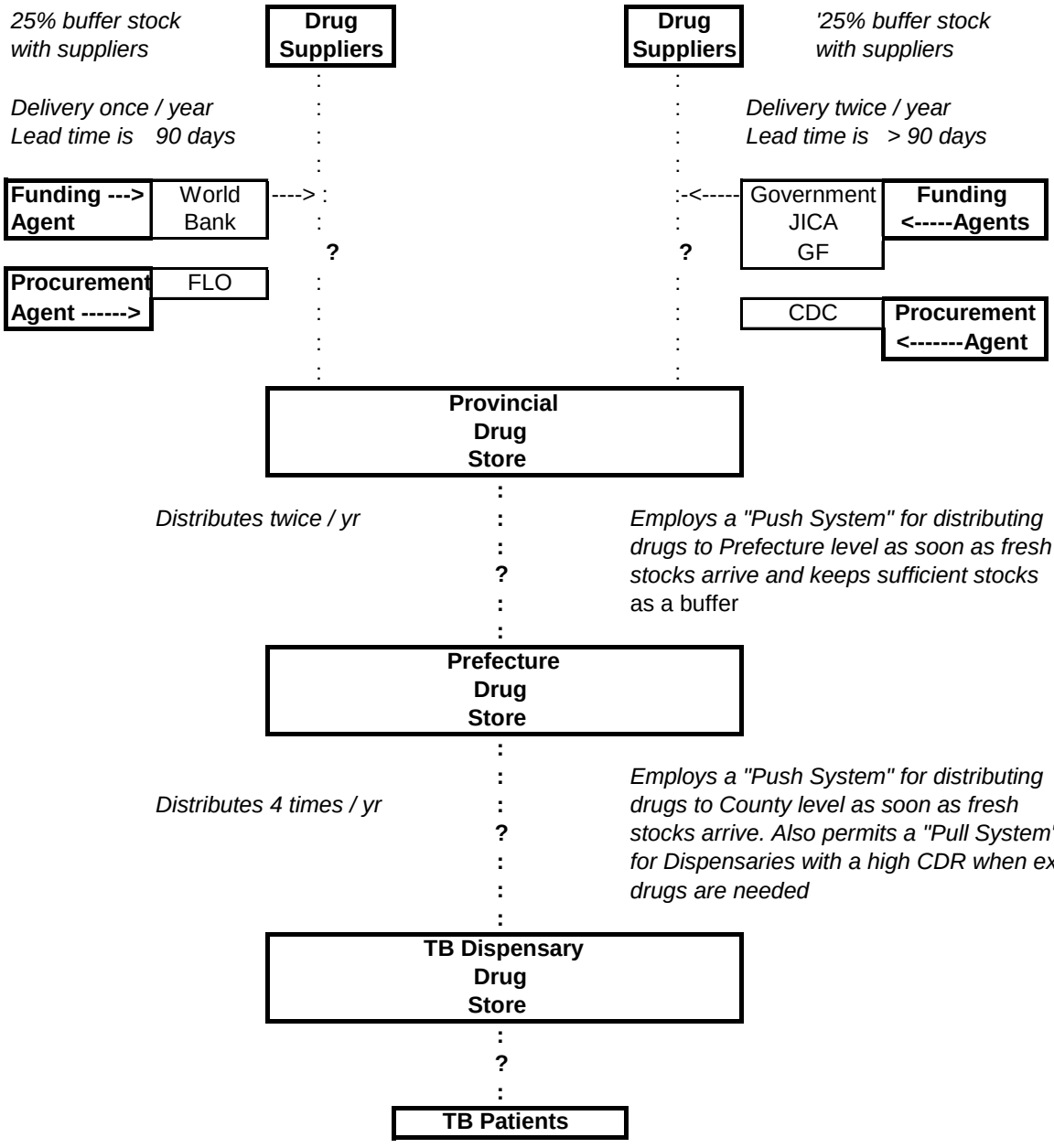
Provide necessary technical assistance for developing proposed new systems and procedures, assistance in their implementation and monitoring performance. The timing of this phase would largely depend on progress made on completing other phases (2 to 4) of the project.

Annex 1. Procurement Quantities and Prices of TB Drugs

No.	Product Name	Unit	JICA /CDC Quantity Oct. 2004	JICA /CDC Price Yuan Oct. 2004	WB / FLO Quantity Oct. 2004	WB / FLO Price Yuan Oct. 2004
1	HRZE	Blister Pack	8,091,045	1.57	789,770	1.99
2	HR	Blister Pack	11,925,315	0.62	1,282,500	0.78
3	HRE	Blister Pack	4,256,445	1.14	354,420	1.44
4	Streptomycin Inj.	Vial	1,631,640	0.31	125,845	0.49
5	Water for Injection	5 cc Vial	1,631,640	0.14		
6	Syringe	5 cc	1,631,640	0.21		

*All prices includes delivery up to the 31 Provincial TB Drug Stores

Annex 2. Flow Diagram of the TB Pharmaceutical Supply System



Annex 3. Tentative Timeline for DMTB Activities

	Activity	Timeline
1	Modify DMTB to suit CDC needs and conditions in China. Develop draft set of indicators, data collection forms, tracer drugs, draft sampling plans and an organization for data collection. This activity is to be completed by MSH and submitted to WHO/CDC prior to 17.01.05	January 2005
2	Finalize survey instruments, sampling plan, data collection forms, tracer drug list and data collection team and a timeline for using DMTB in 2 provinces.	January 2005
3	Recruit data collectors and organize assessment to be undertaken in 2 provinces.	January-February 2005
4	Provide training on use of DMTB, field test in a province close to Beijing, modify DMTB tools based on feedback received from field test.	March 2005
5	Undertake DMTB assessment in 2 provinces and enter data to a suitable database.	March-April 2005
6	Develop indicators, interpret indicators, identify strengths and weaknesses of the TB drug supply system and develop specific interventions for improving TB drug management.	April 2005
7	Prepare DMTB report of findings	May 2005
8	Discuss proposed interventions with key stakeholders and identify a set of interventions to be implemented as a pilot in selected areas	May 2005
9	Develop new systems and procedures to be implemented as a pilot.	May-June 2005
10	Discuss proposed systems with CDC/WHO and finalize their operating characteristics.	June 2005
11	Provide assistance in implementing new systems and monitoring progress.	July-August 2005

Annex 4. Persons Met

Dr. Henk Bekedam	WHO Representative, China
Dr. Daniel P. Chin	Country Advisor Tuberculosis, WHO China
Cai Ji Ming	Senior Research Fellow, Foreign Loan Office, MOH.
Dr. Craig Shapiro	HHS Health Attache, US Embassy, Beijing
Zheng Jin Feng	Chief Physician, CDC Fujian Province
Lai Yuji	National Center for Tuberculosis and Prevention
Liu Haitao	CDC / MOH
Dr. Lin Yan	WHO, China
Sun Jing	WHO China
Prof. Shiming Cheng	NCTB / CDC
Wang Lijiu	Head of Foreign Loan Project Group
Wang Jing	Assistant Project Manager, Damien Foundation
Wang Li Xia	Project Officer, WHO China
Zhang Ben	Vice Director, Foreign Loan Office, MOH.

Annex 5. Scope of Work

Objectives:

The objectives of the pre-assessment for TB drug management in China are to ensure the appropriate scope of and preparations for the full assessment, specifically:

- Meet partners and potential key stakeholders to understand their concerns and interests (what is their expectation for the outcome of the assessment);
- Explain to partners and stakeholders the RPM Plus approach to using assessment results to evaluate options for improving/strengthen pharmaceutical management systems;
- Understand/Be able to describe how the pharmaceutical supply system for the TB program currently functions and identify or confirm potential or perceived weaknesses;
- Determine priorities/criteria for selection of assessment site(s) (provinces, health areas, etc)
- Determine/confirm existing data sources and appropriate data collection methodologies;
- Draft the scope and timeline for a TB drug management assessment, and obtain information needed to develop a work plan and budget.

Activities:

1. Meet with WHO, CDC, National TB program director, provincial TB program managers. The focus of the full assessment will be determined by responses to the following questions. Discuss issues/concerns about pharmaceutical supply management for TB from their perspectives.
    a. Is there a concern about TB drug availability? Have there been reports of stock-outs, irregular supply, or drug expiry? What is known about the problem?
    b. Is there a concern about drug quality? If so, what is the evidence?
    c. Are there any other concerns about access to TB drugs?
        i. Describe any problems in geographic access
        ii. Describe the financing of TB drugs
    d. Are there any known issues related to laboratory supplies and equipment availability related to TB services?
    e. Are there any concerns regarding TB services providers?
        i. Who are the providers or TB services? How many are there? How are they distributed throughout the area? Is there a shortage of providers?
        ii. What is their training?
        iii. Is there a system of supervision?
        iv. Are there any issues of retention?
    f. Is there a concern about recruiting or retaining patients, adherence to therapy, or related drug use problems? Is there evidence?

2. In discussing the above questions, identify relevant stakeholders and relevant contact information.

3. Obtain copies of existing documentation including studies and reports and evaluations. These may be published or unpublished.

4. Conduct field visits to a province and two or three "representative" or typical facilities (as practical) to determine availability of the following sources of data at the relevant levels (provincial offices and facilities):
    a. Requisitions for supplies for at least 12 months (provincial office and facility)
    b. Consumption data for at least 12 months (provincial office and facility)
    c. Inventory status data for at least 12 months (stock cards, cardex, other)
    d. Patient information (what information and where, to determine if treatment records exist and if retrospective treatment review is possible)
        i. Facility-based records – retrospective possible
        ii. Patient cards – prospective most likely
    e. Inquire about perceived problems with TB drug management at the various facilities visited (administrative offices, warehouses, health facilities, patients).

5. Identify potential partners/ subcontractors that may be engaged in the process. For potential subcontracting, determine their capacity, availability, and local costs for participation in RPM Plus activities. Obtain contact information when possible.

Outcomes:

- Objectives and scope of the full assessment will be agreed upon by partners (WHO and CDC)
- Partners will have a shared vision of the objectives of the full assessment.
- Stakeholders will be informed of upcoming assessment and be prepared to contribute

Annex 6. Request for Country Clearance

TO: Lois Bradshaw, Director, USAID Office of HIV/AIDS and Health (HHO), Regional Development Mission/Asia
Matthew Friedman/ Deputy Director, USAID/HHO, Regional Development Mission/Asia

FROM: Management Sciences for Health (MSH)/Rational Pharmaceutical Management Plus (RPM Plus) Program, Cooperative Agreement # HRN-A-00-00-00016-00

SUBJECT: Request for country clearance for proposed travel of MSH/RPM Plus Senior Program Associate Vimal Dias to Beijing, China

COPY: Deborah Seligsohn, Environment, Science, Technology and Health Section (ESTH)/DHHS, US Embassy/China
Craig Shapiro, Health Attaché, ESTH/DHHS, US Embassy/China
Andrew Clements/USAID/ANE Regional Bureau
Anthony Boni/Global HPSR/CTO RPM Plus
Kama Garrison/ USAID
Douglas Keene/Director, MSH/RPM Plus Program

1. The RPM Plus Program wishes to request country clearance for the proposed travel to Beijing, China of MSH/RPM Plus Senior Program Associate Vimal Dias from November 27 through December 6, 2004.

2. **Background**: RPM Plus received a request for technical assistance from WHO/China on issues of TB drug management in FY03. RPM Plus discussions with WHO/China, USAID/RDM/A and USAID/ANE Bureau resulted in a decision to collaborate with WHO/China on these activities. It is envisioned that RPM Plus will conduct an assessment of TB drug management practices in one Chinese province, and, on the basis of those findings, will develop with counterparts a plan of technical assistance support to strengthen TB drug management.

3. **Purpose of Proposed Visit**: RPM Plus will participate in a field visit to Fujian Province to learn about TB drug management at national, provincial, county, and other levels, meet with representatives of the US Embassy, WHO/China, CDC/China, and other organizations to brief them on the proposed RPM Plus approach to assessing TB drug management practices, discuss their perceptions of TB drug management issues and impressions from the field visit, and to plan next steps for conducting the TB drug management assessment in one selected province.

4. **Scope of Work**:

   Vimal Dias will:
   - Provide a briefing/debriefing to health officers of the US Embassy in Beijing or in Bangkok, as requested
   - Meet with representatives of WHO/China, CDC/China, and the National TB program manager to discuss their concerns about pharmaceutical supply management for TB
   - Participate in a field visit to Fujian Province to learn about drug management systems at provincial, county, and local levels and to identify potential sources of data for an assessment
   - Obtain copies of existing documentation regarding drug management aspects of the National TB Program, including studies, reports, and evaluations
   - Identify potential partners/ subcontractors that may be engaged in the process

5. **Anticipated Contacts**: Daniel Chin, WHO/China; representatives of the CDC/China; Deborah Seligsohn and Craig Shapiro, US Embassy/China; other donors and representatives, as required.

6. **Logistics**: Mr. Dias will arrive in Beijing on November 27, 2004, and depart on December 5, 2004. During his visit, Mr. Dias will stay at the Yu Yang Hotel in Beijing. Arrangements are under way for lodging in Fujian province with assistance from WHO/Beijing. No Mission assistance is required.

7. **Funding**: The in-country work will be paid for with USAID/ANE Regional support funds.

8. **Action**: Please advise of country clearance for Mr. Dias as planned. Please confirm receipt and reply via e-mail to the attention of Anthony Boni, USAID/G/PHN/HN/HPSR, at aboni@usaid.gov, tel (202) 712-4789, fax (202) 216-3702, and Andrew Clements, USAID/G/PHN/ANE Regional Bureau, aclements@usaid.gov. Please send carbon copies to Kama Garrison at kgarrison@usaid.gov, Douglas Keene at dkeene@msh.org, Olya Duzey at oduzey@msh.org, and Nicolette Regis at nregis@msh.org.

   Thank you for Mission cooperation.